

July 21, 2021

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Attention: Request for Information Regarding Reporting on
Pharmacy Benefits and Prescription Drug Costs
200 Constitution Avenue, NW
Room N-5653
Washington, DC 20210

Re: Comments on the Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-NC)

Dear Mr. Litton:

The HR Policy Association and the American Health Policy Institute welcomes the opportunity to provide comments to the Department of Labor, the Department of Health and Human Services, and the Department of the Treasury (“the Departments”) on the Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs that was published in the Federal Register on June 23, 2021.¹

The HR Policy Association (“the Association”) is the leading organization representing chief human resource officers of 390 of the largest employers in the United States. Collectively, their companies provide health care coverage to over 20 million employees and dependents in the United States. Association members have struggled for years to get full and complete access to their medical drug spend and pharmacy claims data. They have long backed increasing price transparency to enable employers to reduce health care costs. The American Health Policy Institute, which was created by the Association, has published several reports on the importance of increasing price transparency, including one specifically on the prescription drug supply chain “black box”.²

The Association supports increasing price transparency regarding the pharmacy supply chain. However, the reporting requirements in Section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 (CAA) are placed on employer plans that do not have the required data. Employer plans will have a great deal of difficulty getting the data in some cases. Moreover, it is unclear what value employers will gain relative to the cost of the CAA reporting requirements. While we remain committed to price transparency, we are concerned that the regulatory reporting requirements will place a significant, and often unworkable, burden on employers to provide information they do not have access to.

As an initial matter, the CAA requires employer health plans to report a substantial amount of data that the plans do not have by December 27, 2021. The Association respectfully requests the Departments allow employer plans to make a good faith effort to report whatever data they can

¹ 86 Fed. Reg. 32813.

² These reports are available at <http://www.americanhealthpolicy.org/Studies>.

obtain for the December 27, 2021, and June 1, 2022, reporting dates. Most, if not all, employers will have to modify their pharmacy benefit manager (PBM) contracts, and other third-party administrator or administrative service organization contracts to obtain most of the statutorily required data. Moreover, many large employers have more than one health plan and more than one PBM. Further, some of the data is likely to be subject to contractual disclosure restrictions with other parties in the pharmacy supply chain that will have to be revised. Simply revising the contracts will take a considerable amount of time given all the entities and layers involved in the pharmacy supply chain from manufacturer to pharmacy, not to mention necessary legal counsel.

The Association also strongly recommends the Departments use all the statutory authority they have to require entities in the pharmacy supply chain to provide the required data to employer plans. This data should also be made available to the third-parties employer plans will contract with to report the data to the Departments. There may be some cases where entities in the pharmacy supply chain simply refuse to provide the data to employer plans for proprietary reasons. Unfortunately, the statute does not compel drug manufacturers, PBMs, other entities in the pharmacy supply chain, or medical providers to disclose information solely in their possession (*i.e.*, there is no penalty for not providing the data to employer plans).³ The liability for failing to report falls on employer plan sponsors. This raises several questions: What happens to plan sponsors if they cannot get the information from their vendor(s)? What happens if a vendor does not provide accurate data? The Department should address these issues in the proposed rule.

For small employer plans, maintaining the privacy of plan participants at the level of granularity required by the statute, even if the data is deidentified, represents a potential privacy concern. The Departments should be cognizant of this issue when developing a proposed rule and consider steps to avoid the problem.

To assist the Departments in preparing a proposed rule, the Association respectively provides the following comments.

CAA Reporting Requirements

The statute requires employer group health plans to submit to the Departments the following information with respect to the health plan or coverage in the previous plan year.

- The plan year, the number of plan participants, and a list of each state in which the plan is offered.
 - *The Departments need to recognize that 25% of small firms and 57% of large firms have more than one plan and 6% of small firms and 12% of large firms have three or more plan types.⁴ While the statute appears to require reporting by “group health plan”, employers should have the option to provide one report if that would simplify their reporting burdens and costs.*

³ Notably, Section 201 of Title II of Division BB of the Consolidated Appropriations Act, 2021, prohibits employer health plans from entering into an agreement with a health care provider that include “gag clauses.” However, Section 201 does not appear to apply to entities in the pharmacy supply chain.

⁴ Kaiser Family Foundation, Employer Health Benefits 2020 Annual Survey, Figure 4.1.

- The 50 brand drugs most frequently dispensed by pharmacies for claims paid by the plan and the total number of paid claims for each such drug.
 - *This is the only provision in the section that refers to “brand” prescription drugs. Other provisions refer to “prescription drugs.” This suggests Congress intended to NOT include generic prescription drugs in this reporting requirement.*
 - *For the information to be of any use, the claims data needs to be standardized. The number of days supplied is better than the number of claims because the number of days supplied provides more insight into how these drugs are dispensed.*
- The 50 most costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug.
 - *This broader language suggests Congress intended to include generic prescription drugs in this reporting requirement.*
 - *For the information to be of any use, the claims data needs to be standardized. The Association recommends cost per day be the measure reported here as it provides insight into the differences in retail prices for the specific drugs.*
- The 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year.
 - *Again, this broader language suggests Congress intended to include generic prescription drugs in this reporting requirement.*
 - *To ease first-year reporting burdens and costs, the Association requests employers have the option to delay this reporting requirement until year two.*
- Total spending on health care services by the plan broken down by: 1) the type of cost including hospital costs; health care provider and clinical service costs, for primary care and specialty care separately; the costs for prescription drugs; and other medical costs, including wellness services; and spending on prescription drugs by the health plan or coverage; and the enrollees.
 - *While this statutory language is very prescriptive, the Association recommends the Departments define these categories as follows: Inpatient costs; Outpatient costs broken down by primary care and specialty care; Pharmacy costs; and all other health care costs including administration and wellness services.*
 - *Hospital costs, health care provider and clinical service costs for primary care and specialty care are likely to include prescription drug costs. It is unclear if employer plans can get this data from their third-party administrators or if third party administrators can even get this data from hospitals and other medical providers.*
- Average monthly premium and the associated employer/participant responsibilities.
 - *This requirement is complicated for high-deductible health plans (HDHP)/Health Savings Accounts (HSA) plans, especially if you want to be able to compare them to other employer plans. For example, how should individual and employer*

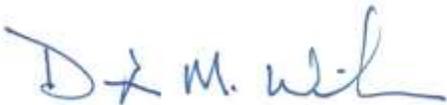
contributions to the HSA be counted? The Kaiser Family Foundation annual survey of employer health benefits does not include contributions made by the employer to HSAs or Health Reimbursement Arrangements (HRAs).⁵

- Any impact on premiums or out-of-pocket costs relating to rebates, fees, etc. paid by drug manufacturers to the plan or its administrators or service providers, with respect to prescription drugs prescribed to enrollees in the plan, including the amounts so paid for each therapeutic class of drugs; and the amounts so paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan coverage from drug manufacturers during the plan year. Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration described in the previous bullet.
 - *This is likely to be the most problematic reporting requirement for employer plans. As noted above, entities in the pharmacy supply chain may simply refuse to provide the data to employer plans for proprietary reasons. Drug manufacturers use rebates to incentivize certain stakeholders, in this case PBMs and wholesalers, to stimulate demand for a certain drug (i.e., include the drug on a formulary). This incentive is often necessary because rebates are typically used for high-cost brand drugs in competitive therapeutic classes.⁶ Rebates tend to be considered trade secrets and vary depending on the drug manufacturer, plan sponsor, and drug brand. This secrecy creates a “black box” in the distribution chain in that the patient and the insurer do not have access to information regarding how much manufacturers are paying in rebates as well as how much of a particular rebate the PBM is keeping before passing along the rebate to the insurer. The Association strongly recommends the Departments use its statutory authority to require entities in the pharmacy supply chain to provide the required data to employer plans and the third-parties employer plans will contract with to report the data to the Departments.*

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The Association supports efforts to increase price transparency in our health care system. However, the reporting requirements place a significant burden on employers. We urge the Departments to consider these recommendations when developing a proposed rule and we look forward to working with you to implement this statutory reporting requirement in the most effective, least burdensome way.

Sincerely,



D. Mark Wilson
President & CEO, American Health Policy Institute
Vice President, Health & Employment Policy, HR Policy Association

⁵ Kaiser Family Foundation, Employer Health Benefits 2020 Annual Survey, page 81, footnote 1.

⁶ AMCP. Maintaining the Affordability of the Prescription Drug Benefit: How Managed Care Organizations Secure Price Concessions From Pharmaceutical Manufacturers.